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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/477,730	01/05/2000	KOICHI SUGITA	4859-0029-0	9663

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 11/04/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/477,730	Applicant(s) SUGITA ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response filed August 21, 2002, paper no. 12, has been entered.

Claims 1-13 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-5 and 7-13 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed March 21, 2002.

Applicant's arguments filed August 21, 2002, have been fully considered but they are not persuasive.

Applicant argues that page 10 of the specification provides a detailed description of plant hormone signal transduction genes, and that merely providing the names of these genes provides the required structural and functional description of these sequences because they are known in the art (reply pages 5-6).

The Examiner disagrees that merely providing the names of plant hormone signal transduction genes provides the structural and functional description necessary to support the claimed invention. The claims are not limited to plant hormone signal transduction genes, but rather are directed to plant hormone signal transduction genes that function as selectable marker

genes. The Examiner maintains that the specification describes only one plant hormone signal transduction gene that can function as a selectable marker gene, the cytokinin signal transduction gene CKI1.

Claims 1-5 and 7-13 remain rejected under 35 U.S.C. 112, first paragraph, for scope of enablement, for the reasons of record set forth in the office action mailed March 21, 2002.

Applicant's arguments filed August 21, 2002, have been fully considered but they are not persuasive.

Applicant argues that the specification provides a detailed description of how to make and use the claimed vector. Applicant also argues that the specification provides a detailed description of plant hormone signal transduction genes at page 10, that the working examples at pages 27-45 provide specific details regarding how to make the claimed vector and select the transformed tissue, and that one skilled in the art could, without undue experimentation, readily prepare and use other vectors within the scope of the claims (reply page 6).

The Examiner maintains that undue experimentation would be required to practice the full scope of the claimed invention, because the specification does provide sufficient guidance for one skilled in the art to determine which plant hormone signal transduction gene could be used as a selectable marker gene. While the specification identifies a number of different known plant hormone signal transduction genes, the specification does provide sufficient guidance with respect to which of these genes may be used as a selectable marker gene, as the use of any gene as a selectable marker gene is unpredictable, and the specification discloses only one plant

hormone signal transduction gene that may be used as a selectable marker gene, the CKI1 gene of *Arabidopsis*.

Applicant additionally argues that the Examiner is incorrect to assert that plant hormone signal transduction proteins would be detoxified, because the Examiner confuses degradation and detoxification, as degradation does not always involve detoxification, and detoxification does not always involve degradation. Applicant argues that one skilled in the art can easily understand that the protein is not subjected to detoxification in plant cells, and that proteins that function in signal transduction pathways are indispensable for growth and differentiation and would naturally be destined to exist in various plant cells (reply pages 6-7).

The Examiner does not dispute that degradation does not always involve detoxification, and detoxification does not always involve degradation. However, the Examiner maintains that while plant cells in general would be expected to contain proteins that function in signal transduction pathways at some point in time or under certain circumstances, the presence of any specific signal transduction protein in any specific plant cell type at a specific time or under specific circumstances would depend on the cell's metabolism with respect to the specific signal transduction protein in question.

Claim Rejections - 35 USC § 103

Claims 1-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent No. 0 716 147 (12 June 1996, Applicant's IDS) in view of Kakimoto et al. (8 November

1996, Science, Vol. 274, pages 982-985, Applicant's IDS), for the reasons of record set forth in the office action mailed March 21, 2002.

Claims 1-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,965,791 (12 October 1999) in view of Kakimoto et al. (8 November 1996, Science, Vol. 274, pages 982-985, Applicant's IDS), for the reasons of record set forth in the office action mailed March 21, 2002.

Applicant's arguments filed August 21, 2002, have been fully considered but they are not persuasive.

Applicant argues that he references fail to suggest the claimed vector. With respect to the cited reference of Kakimoto et al., Applicant argues that one reading the reference would conclude that the purpose of the vector described therein was to express CKI1, and that therefore CKI1 was the desired gene. Applicant also argues that one reading the reference would conclude that the additional genes of the Ti plasmid were present to assist and direct the expression of CKI1, not that they were the desired genes to be expressed. Additionally, Applicant points out that Kakimoto et al. used an antibiotic resistance gene as a selectable marker gene. Applicant argues that since Kakimoto et al. fail to disclose a desired gene which is not a plant hormone signal transduction gene, since Kakimoto et al. used an antibiotic resistance gene as a selectable marker gene, and since CKI1 is not used as a selectable marker gene by Kakimoto et al., Kakimoto et al. fail to disclose a plant hormone signal transduction gene as a selectable marker gene (reply pages 2-4).

With respect to "desired gene", the Examiner maintains that the claims do not specify what a desired gene is, but only what a desired gene is not, namely a desired gene is not a

selectable marker gene. The broadest reasonable interpretation of "desired gene" would be any gene whose presence or expression would be desirable. Accordingly, any of the additional genes of the Ti plasmid into which the plant hormone signal transduction gene was cloned would constitute a "desired gene". With respect to "plant hormone signal transduction gene as a selectable marker gene", the Examiner maintains that it is not necessary that Kakimoto et al. teach that CKI1 is a selectable marker gene, or use CKI1 as a selectable marker gene, as the ability of CKI1 to function as a selectable marker gene is an inherent feature of the CKI1 gene.

Applicant further argues that the experimental data set forth in the specification is striking evidence of nonobviousness as evidenced by the unexpected effect that selection efficiency can be improved by using a plant hormone signal transduction gene as a selectable marker gene.

U.S. Patent No. 5,965,791 was cited with respect to the use of a removable DNA element in a plant transformation vector to enable the removal of a selectable marker gene from transgenic plants. The Examiner maintains that because US 791 does not employ a plant hormone signal transduction gene, and because all of the vectors of the claimed invention do employ a plant hormone signal transduction gene, the relevant comparison for selection efficiency would be between the vectors of the instant invention and the vector of Kakimoto et al., which does employ a plant hormone signal transduction gene.

Double Patenting

Claims 1-9 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 6, and 7 of U.S. Patent No. 5,965,791 in view of Kakimoto et al. (8 November 1996, Science, Vol. 274, pages 982-985, Applicant's IDS), for the reasons of record set forth in the office action mailed March 21, 2002.

Applicant's arguments filed August 21, 2002, have been fully considered but they are not persuasive.

Applicant traverses the double patenting rejection on the grounds stated previously under 35 USC 103 with respect to the Kakimoto et al. reference (reply page 5).

The Examiner maintains that Applicant's arguments are not persuasive for the reasons set forth above in response to the traversal of the rejection made under 35 USC 103.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
October 29, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600